

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: Anand R. Baichwal
Serial No.: Not yet assigned
Filed: Herewith
For: **SUSTAINED RELEASE MATRIX FOR HIGH-DOSE
INSOLUBLE DRUGS**

INFORMATION DISCLOSURE STATEMENT

Mail Stop: Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 9, 2003

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicant hereby makes of record the documents listed on the accompanying Form PTO-1449 (9 pages) for consideration by the Examiner in connection with the examination of the above-identified patent application.

The Examiner's attention is respectfully directed to pages 1 to 8 of the present Form PTO-1449, which are copies from Information Disclosure Statements filed during the prosecution of parent Application Serial Nos. 09/842,289; 09/420,247, now U.S. patent No. 6,245,355 and 08/889,424, now U.S. Patent No. 6,093,420.

The Examiner's attention is also directed to the 9th page of the Form PTO-1449 which lists U.S. Patent No. 5,330,761 and Remington's Pharmaceutical Sciences, references cited by the examiner during prosecution of the '247 Application.

Pursuant to 37 C.F.R. § 1.98(d), copies of these references of record in the parent applications are not enclosed. If it is determined that any of the listed references are not of record in the parent applications, the Examiner is requested to contact the undersigned so that a copy

can be forwarded.

Applicant also respectfully advises the Examiner of the following U.S. Patents and U.S. Applications which are commonly assigned to the owners of the instant application:

U.S. Patent No. 5,662,933, "Controlled Release Formulation (Albuterol)", issued September 2, 1997;

U.S. Patent No. 5,958,456, "Controlled Release Formulation (Albuterol)", issued September 28, 1999;

U.S. Patent No. 6,056,977, "Novel Once-A-Day Controlled Release Sulfonylurea Formulation", issued May 2, 2000;

U.S. Patent No. 6,537,578, "Novel Once-A-Day Controlled Release Sulfonylurea Formulation", issued March 25, 2003;

U.S. Patent Application Serial No. 10/396,114, "Novel Once-A-Day Controlled Release Sulfonylurea Formulation", filed March 25, 2003;

U.S. Patent No. 5,455,046, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued October 3, 1995;

U.S. Patent No. 5,512,297, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued April 30, 1996;

U.S. Patent No. 5,554,387, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued September 10, 1996;

U.S. Patent No. 5,667,801, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued September 16, 1997;

U.S. Patent No. 5,846,563, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued December 8, 1998;

U.S. Patent No. 6,136,343, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", issued October 24, 2000;

U.S. Patent Application No. 09/654,691, "Sustained Release Heterodisperse Hydrogel Systems for Insoluble Drugs", filed September 5, 2000;

U.S. Patent No. 5,773,025, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued June 30, 1998;

U.S. Patent No. 6,048,548, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued April 11, 2000; and

U.S. Patent No. 6,245,356, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", issued June 12, 2001;

U.S. Patent Application No. 09/879,296, "Sustained Release Heterodisperse Hydrogel Systems-Amorphous Drugs", filed June 12, 2001;

This Information Disclosure Statement is filed under 37 C.F.R. §1.97 (c), after the period specified in 37 C.F.R. §1.97 (b) but before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R § 1.311. Accordingly, enclosed is a check for \$180.00 in satisfaction of the fee due under 37 C.F.R. § 1.17 (p).

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. It is respectfully submitted that the pending claims are patentable over all of the references made of record at this time.

In the event any additional fee is due in connection with this response or if any fee has been overpaid, the deficiency or overpayment should be charged to our Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Cary S. Kappel
Reg. No. 36,561

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(212) 736-1940

PATENT AND TRADEMARK OFFICE										ATTY. DOCKET No. 540.1020CON3					SERIAL NO.: To be Assigned				
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)										APPLICANT: Anand R. Baichwal									
										FILING DATE: Herewith					GROUP: To be Assigned				
U.S. PATENT DOCUMENTS																			
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	AA	4	8	0	3	0	8	1	2/7/89	Falk, et al.	424	488							
	AB	4	8	9	4	2	3	5	1/16/90	Kohne, et al.	424	452							
	AC	5	1	0	8	7	5	7	4/28/92	Erdos, et al.	424	451							
	AD	5	5	5	4	3	8	7	9/10/96	Baichwal	424	488							
	AE	4	1	9	1	7	7	2	3/4/80	Woog, et al.	424	273R							
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	AF	8	5	0	4	1	0	0	9/26/85	PCT A1	A61K	9/40	X						
	AG	9	4	2	3	7	0	0	10/27/94	PCT A1	A61K	9/16	X						
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	AI	3	4	0	0	1	0	6	7/11/85	Germany A1	A61K	9/00	Abstract						
OTHER REFERENCES CITED (Including Author, Title, Date, Pertinent Pages, Etc.)																			
	AJ	Chemical Abstracts, Vol. 104 (1986) Abstract 174662y																	
	AK	Chemical Abstracts, Vol. 99 (1983) Abstract 128360d																	
	AL	Chemical Abstracts, Vol. 92 (1980) Abstract 135278s																	
	AM	Chemical Abstracts, Vol. 92 (1980) Abstract 82429h																	
	AN	Chemical Abstracts, Vol. 77 (1972) Abstract 39130g																	
	AO	Chemical Abstracts, Vol. 70 (1969) Abstract 17133p																	
	AP	Chemical Abstracts, Vol. 98 (1983) Abstract 221832y																	
	AQ	Alderman, D.A., "A review of cellulose ethers in hydrophilic matrices for oral controlled-release dosage forms", <u>Int. J. Pharm. Tech. & Prod. Mfg.</u> , Vol 5, pages 1-9 (1984)																	
	AR	Haynes, R. Brian, M.D., et al., "Manipulation of the therapeutic regimen to improve compliance: Conceptions and misconceptions", <u>Clinical Pharmacology and Therapeutics</u> , Vol. 22, No. 2, (August 1977)																	
	AS	English translation of Japanese Patent Laid-Open-To-Public, publication no. 8/1986, publication date 1/6/86, Japanese Patent Application No. 118,789/1984; Japanese Patent Application date: 6/9/84																	
	AT	<u>Techniques of Solubilization of Drugs</u> , edited by Samuel H. Yalkowsky, The Upjohn Company, pub. Marcel Dekker, Inc., New York and Basel, pages 308-315 (1981)																	
EXAMINER										DATE CONSIDERED									
<small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>																			

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	BA	3	4	8	5	8	4	7	12/23/69	Bossert, F., et al.	260	295.5					
	BB	3	7	8	4	6	8	4	1/8/74	Bossert, F., et al.	424	37					
	BC	4	6	6	5	0	8	1	5/12/87	Doi, et al.	514	356					
	BD	4	8	8	9	7	2	3	12/26/89	Kim, et al.	424	450					
	BE	4	9	8	3	5	9	3	1/8/91	Miyajima, et al.	514	110					
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	BG	0	0	4	7	8	9	9	3/24/82	EPO (A1)	A61K	9/14	Abstrac				
	BH	0	1	4	7	1	7	1	7/3/85	EPO (A2)	C07D	401/12	X				
	BI	2	1	0	1	6	8	0	2/6/94	Canada (A1)	A61K	31/44	X				
OTHER REFERENCES CITED (Including Author, Title, Date, Pertinent Pages, Etc.)																	
	BJ	"Crystallization and Granulation", Remington's Practice of Pharmacy, 9th Ed. Chapter XXVII, pages 208-211, 1950															
	BK	Ritschel, Angewandte Blopharmazie, pages 293-302 (1973)															
	BL	Sugimoto, I., et al., "Dissolution and Absorption of Nifedipine From Nifedipine-Polyvinylpyrrolidone Coprecipitate", <u>Drug Development and Industrial Pharmacy</u> , Vol. 6, No. 2, pages, 137-161 (1980).															
	BM	Kleinbloem, M., et al., Nifedipine: Kinetics and dynamics in healthy subjects", <u>Chin. Pharmacol. Ther.</u> , Vo. 35, No. 6, pages 742-749 (1984)															
	BN	Ramasch, K., et al., "Pharmacokinetics and Metabolism of Nifedipine", <u>Hypertension Supplement II</u> , Vo. 5, No. 4, July-August 18-24 (1983)															
	BO	McGinity, J.W., et al., "Dissolution and Uniformity Properties of Ordered Mixes of Micronized Griseofulvin and a Directly Compressible Excipient", <u>Drug Development and Industrial Pharmacy</u> , Vol. 11, No. 4, Pages 891-900 (1985)															
	BP	Helbig, J., et al. "Pharmaceutical oral dosage forms of an active agent capable of forming or releasing bicarbonate ions", <u>Pharmaceuticals</u> , (Abstract-98:221837d), vol. 98, page 63 (1983)															
	BQ	The Merck Index, pages 848-849, 9th Ed. (1976)															
	BR	D.Q.M.Craig, "Polyethylene Glycols and Drug Release", <u>Drug Development and Industrial Pharmacy</u> , 16(17), Pages 2501-2526 (1990)															
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	CB	5	1	2	8	1	4	2	7/7/92	Mulligan, et al.	424	457			
	CC	5	1	1	0	6	0	2	5/5/92	Kim, et al.	424	451			
	CD	5	1	6	0	7	3	4	11/3/92	Ganesan, et al.	424	78.38			
	CE	5	2	6	4	4	4	6	11/23/93	Hegasy, et al.	514	356			
	CF	4	4	1	2	9	8	6	11/1/83	Kawata, et al.	424	80			
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	CH	4	6	7	3	5	6	4	6/16/87	Kawata, et al.	424	494			
	CI	4	7	6	4	3	8	2	8/16/88	Kydonieus, et al.	424	449			
	CJ	4	7	6	5	9	9	0	8/23/88	Sugimoto, et al.	424	494			
	CK	4	7	9	2	4	5	0	12/20/88	Kydonieus, et al.	424	449			
	CL	4	7	9	2	4	5	2	12/20/88	Howard, et al.	424	475			
	CM	4	8	0	8	4	1	3	2/28/89	Joshi, et al.	424	458			
	CN	4	8	5	1	2	2	9	7/25/89	Magruder, et al.	424	457			
	CO	4	8	6	7	9	8	5	9/19/89	Heafield, et al.	424	461			
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	CP	2	1	6	0	1	0	0	12/18/95	Great Britain (A)	A61K	9/22	X		
	CQ														
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	DA	5	4	3	9	6	8	7	8/8/95	Compassi	424	468			
	DB	5	4	7	6	6	5	4	12/19/95	Conte, et al.	424	78.08			
	DC	4	8	9	2	7	4	1	1/9/90	Ohm, et al.	424	479			
	DD	4	9	0	4	6	9	9	2/27/90	Bauer	514	972			
	DE	4	9	4	0	5	8	7	7/10/90	Jenkins, et al.	424	480			
	DF	4	9	4	2	0	4	0	7/17/90	Ragnarsson, et al.	424	486			
	DG	4	9	7	3	4	6	9	11/27/90	Mulligan, et al.	424	461			
	DH	4	9	9	4	2	7	6	2/19/91	Baichwal, et al.	424	440			
	DI	5	0	0	7	7	9	0	4/16/91	Shell	424	451			
	DJ	5	0	1	9	3	9	7	5/28/91	Wong, et al.	424	473			
	DK	5	0	5	1	2	6	3	9/24/91	Barry, et al.	424	490			
	DL	5	0	7	1	6	4	2	12/10/91	Lahr, et al.	424	474			
	DM	5	1	2	8	1	4	3	7/7/92	Baichwal, et al.	424	464			
	DN	5	1	3	2	1	1	6	7/21/92	Soumac, et al.	424	469			
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	DP	0	3	5	7	7	9	3	3/14/90	EP (A1)					
	DQ	W O	89	0	2	7	3	8	4/6/89	PCT					
	DR	W O	92	0	6	6	8	0	4/30/92	PCT					
	DS	1	2	8	8	0	4	9	8/27/91	Canada					
OTHER REFERENCES CITED (Including Author, Title, Date, Pertinent Pages, Etc.)															
	DJ														
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	EC	5	1	4	5	6	8	3	9/8/92	Rhodes	424	451				
	ED	5	1	6	9	6	3	8	12/8/92	Dennis, et al.	424	457				
	EE	5	2	1	5	7	5	8	6/1/93	Krishnamurthy	424	488				
	EF	5	2	6	4	4	5	9	11/23/93	Chelmick-Schorr, et al.	514	646				
	EG	5	2	7	3	7	6	0	12/28/93	Ohslack, et al.	424	480				
	EH	5	2	8	6	4	9	3	2/15/94	Oshlack, et al.	424	468				
	EI	5	3	5	6	4	6	7	10/18/94	Oshlack, et al.	106	153				
	EJ	5	4	5	5	0	4	6	10/3/1995	Baichwal	424	457				

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		FC	5	1	6	9	6	3	9	12/8/92	Baichwal			424		468				
		FD	5	0	9	1	1	9	0	2/25/92	Kuczynski, et al.			424		473				
		FE	5	6	6	7	8	0	1	9/16/97	Baichwal			424		457				
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		FG	5	5	1	2	2	9	7	4/30/96	Baichwal			424		451				
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	GN	5	5	4	3	0	9	9	3/6/96	Zhang, et al.	264	115					
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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 540.1020CON3		SERIAL NO.: To be Assigned						
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To be Assigned**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	IA	5	3	3	0	7	6	1	July 1994	Baichwal	424	469	
	IB												
	IC												
	ID												
	IE												
	IF												
	IG												
	IH												
	II												
	IJ												
	IK												

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	IL	1	3	1	3	1	3	3	1/26/93	Canada	A61k	9/22		
	IM	2	1	2	4	3	5	3	09/30/93	Canada	A61k	9/22		
	IN	2	1	3	1	6	4	7	08/10/99	Canada	A61k	9/22		
	IO	2	0	3	4	0	9	6	07/16/91	Canada	A61k	31/19		
	IP													

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	IR	Remington's Pharmaceutical Sciences, 18 th edition, Mack Publishing Company, 1990, pp 1634
	IS	
	IT	

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